

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,674	02/15/2001	Karen W. Shannon	10971464-3	3167
7590 06/07/2002 AGILENT TECHNOLOGIES			EXAMINER	
Legal Departme			MAHATAN, CHANNING	
P.O. Box 58043 Santa Clare, CA 95052-8043			ART UNIT	PAPER NUMBER
Santa Clare, CA	4 <i>93032-</i> 0043		1631 DATE MAILED: 06/07/2002	7

Please find below and/or attached an Office communication concerning this application or proceeding.



# Office Action Summary

No.	Applicant(s)
Application No.	1
-1074	SHANNON ET AL.
09/784,674	a Allait
Examiner	Art Unit
1	1631
Channing S. Mahatan	the correspondence address

The MAILING DATE of this communication app	Channing S. Mahatan	1631 rrespondence address
TE of this communication app	ears on the cover sheet with the	· •
The MAILING DATE of this community	- ANONTHIS	S) FROM
Period for Reply	IS SET TO EXPIRE 1 MOINTING	,,
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. THE MAILING DATE OF THIS COMMUNICATION.	acco. In no event, however, may a reply be time	ely filed
THE MAILING DATE OF THE MA	30(a). III 110 0 0 0 1 1 1	will be considered timely.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

  If the period for reply specified above is less than thirty (20) days a configuration of the period for reply specified above is less than thirty (20) days a configuration.

	THE MA  - Extension after SIX  - If the per - If NO per - If NO per	ons of time may be X (6) MONTHS from priod for reply specific eriod for reply is significant to reply within the	available under the provisions on the mailing date of this comm	CATION. of 37 CFR 1.136(a). In no event, howen nunication. 00) days, a reply within the statutory mir latutory period will apply and will expire y will, by statute, cause the application to after the mailing date of this communication.	over, may a reply be timely lited himum of thirty (30) days will be SIX (6) MONTHS from the mail to become ABANDONED (35 U atton, even if timely filed, may re	considered timely. ing date of this communication. .S.C. § 133). aduce any	
Sta	atus		indian(s) f	filed on:			
	1)[]	Responsive	to communication(s) f	2b)⊠ This action is non-	final.	io.	
	-)□ 2a)□		- FINIAL	20)23 11	formal matters, prosec	cution as to the ments is	
	3)[]	Since this a	pplication is in condition is in condition in the practice with the practice in the practice i	on for allowance except for actice under <i>Ex parte Quayl</i> e	e, 1935 C.D. 11, 400 C	,	
_	· a a i t i						
D	sposiu	011 01 01	404 is/are pending in t	he application.	43		1
	4)⊠	Claim(s) 1-	1 <u>01</u> is/are pending in t	s/are withdrawn from consid	eration.		
		4a) Of the a	ic/ore allowed.				
	5)	Claim(s)	is/are allowed.				1
	6)[	Claim(s)	is/are rejected.				
	7)	Claim(s) _	is/are objected to	riction and/or election requ	irement.		
	8)🛛	Claim(s) 1	<u>101</u> are subject to res	(HOLIOH GHA)			
	Annlica	tion Papers					
	مرات	Teles anacifi	cation is objected to b	y the Examiner. are: a)☐ accepted or b)☐ ot v objection to the drawing(s) b	piected to by the Exami	ner.	
			arcal filed on 15/1	arc. u/L	s held in abevance. See	37 CFR 1.85(a).	
1	10)L_	The urawii	may not request that an	are: a)□ accepted or b)□ of y objection to the drawing(s) b n filed on is: a)□ app are required in reply to this Offic	wayod h\ disapprov	ed by the Examiner.	
-							
					ce action.		
		If approv	ed, corrected diaming	ed to by the Examiner.			
	12)[	The oath (	or declaration is object	0			
	Priorit	ty under 35	U.S.C. §§ 119 and 12	<b>0</b> claim for foreign priority und e of:	ler 35 U.S.C. § 119(a)	<sub>1</sub> -(d) or (t).	
	13)	☐ Acknowle	edgment is made of a	Claim for foreign Pro			
	,	OLD All b)	「 Some " c) L」 Non		a received.		
		. 🗆 🔾	adified conies of the p	Money documents	n received in Applicati	on No	
		2□ 0	ertified copies of the p	copies of the priority docume International Bureau (PCT	ents have been receive	ed in this National Stage	
			c - d o	SONIAS NI IIIE DITOTILI	- · 47 O/o\\		
		3	application from the	copies of the priority docume International Bureau (PCT e action for a list of the cert claim for domestic priority u	ified copies not receive	ed. (e) (to a provisional application ceived. 20 and/or 121.	on).
		* See the	allaulieu dolanda of a	claim for domestic priority u	inder 35 U.S.C. § 119	opived	
	14	) ☐ Acknowle	edgment is made of a	claim for domestic priority c eign language provisional a a claim for domestic priority	pplication has been re	on and/or 121.	
		a) 🔲 Th	e translation of the for	eign language provisional a I claim for domestic priority	under 35 U.S.C. §§ 12	O diles et :-	
	15	5) Acknow	ledgment is made or a	- <del></del>			
		chment(s)				ary (PTO-413) Paper No(s)	

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

6) Other: Attachment for PTO-948.

Art Unit: 1631

# **DETAILED ACTION**

ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicants are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

OBJECTION BY DRAFTSMAN

Applicants are hereby notified that the required timing for correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicants required to submit drawing corrections with the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

SEQUENCE COMPLIANCE

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a) (1) and (a) (2). This application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 due to the sequence as in the specification on page 46, line 4, etc., and no submission of the following items. Therefore, applicant is required to submit the following:

- 1. As a separate part of the disclosure on paper copy or compact disk copy, a "Sequence Listing" as 37 C.F.R. § 1.821(c).
- 2. A copy of the "Sequence Listing" in computer readable form as required by 37 C.F.R. § 1.821 (e).

3. A statement that the content of the paper and computer readable copies are the same and include no new matter, as required by 37 C.F.R. § 1.821 (f) and 37 C.F.R. § 1.821 (g).

4. Each sequence in the specification is required to have a SEQ ID NO. therewith.

Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. A complete response to this office action includes compliance with this sequence rule compliance requirement. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this office action.

## Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-40 and 98-101, drawn to methods for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence utilizing a predetermined number of unique oligonucleotides within a nucleotide sequence, classified in class 702, subclass 20; and class 435, subclass 6. If this Group is elected, then the below summarized species elections are also required.
- II. Claims 41-97, drawn to methods for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence utilizing a set of overlapping oligonucleotides from a nucleotide sequence, classified in class 702, subclass 20; and class 435, subclass 6. If this Group is elected, then the below summarized species elections are also required.

Art Unit: 1631

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-II each are directed to distinct methods of predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence. In Invention I a predetermined number of unique oligonucleotides within a nucleotide sequence are identified. In Invention II a set of overlapping oligonucleotides from a nucleotide sequence are identified/obtained. Invention I does not indicate that the oligonucleotides utilized are overlapping, further Invention II does not indicate that the oligonucleotides utilized are predetermined. It is acknowledged that the above methods for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence are classified within the same class and subclass, however such classification does not exclude such processes from restriction since it is shown that each invention contains divergent subject matter, and are distinctly different processes (directed to differing procedures as well as results). Each of these differing procedures requires a distinct search thus documenting the undue search burden if searched together.

FIRST SPECIES ELECTION GROUP APPLICABLE ONLY IF GROUP I OR II IS ELECTED

This application contains claims directed to the following patentably distinct species of the claimed invention:

- IA. Composition factors; claims 5, 6, 47, and 48.
- IB. Thermodynamic factors; claims 5, 7, 47, 49, 78, 79, and 82.
- IC. Chemosynthetic efficiencies; claims 5, 8, 47, and 52.
- ID. Kinetic factors; claims 5, 9, 47, and 53.

Currently, claims 1-5, 10-47, 50, 51, 54-77, 80, 81, and 83-101 are generic to all of the above species IA-ID. The following are definitions to the above distinct species, which justifies

Art Unit: 1631

and forms the basis of the species election requirement: IA. Composition factors are numerical factors based solely on the composition of sequence of an oligonucleotide without involving additional parameters (page 20, lines 27-29 of the Specification). IB. Thermodynamic factors are numerical factors that predict the behavior of an oligonucleotide in some process that has reached equilibrium (page 21, lines 10-13 of the Specification). IC. Chemosynthetic efficiencies are the observed efficiency of hybridization between an oligonucleotide and its complementary target (page 22, lines 1-8 of the Specification). ID. Kinetic factors are numerical factors that predict the rate at which an oligonucleotide hybridizes to its complementary sequence or the rate at which the hybridized sequence dissociates from its complement (page 22, lines 12-14 of the Specification). Thus, the search for the above species IA-ID is reasonably non-overlapping thus documenting this specie election requirement due to the undue search burden that would exist if the search for prior art covered these non-overlapping species together.

SECOND SPECIES ELECTION GROUP APPLICABLE ONLY IF GROUP I OR II IS ELECTED

This application contains claims directed to the following patentably distinct species of the claimed invention:

IIA. Non-chemically modified nucleotides; claims 17, 18, 20, 21, 60, 61, 63, 64, 87, 88, 90, and 91.

IIB. Chemically modified nucleotides; claims 19, 22, 62, 65, 89, and 92.

Currently, claims 1-16, 23-59, 66-86, and 93-101 are generic to all of the above species IIA and IIB. Chemically modified nucleotides are nucleic acid polymers containing a modified base, sugar or phosphate group (page 17, lines 12-16 of the Specification). Chemical modification of nucleotides alters nucleotide function/composition to the extent that the above

Art Unit: 1631

species are considered distinct. Thus, the search burden for the above species are nonoverlapping thus supporting this specie election requirement due to an undue search burden if the species were examined together via two separate searches.

Applicants are required under 35 U.S.C. § 121 to elect a single disclosed species for "each" of the above specie sets for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Art Unit: 1631

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

#### INVENTORSHIP AMENDMENT

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

### **EXAMINER INFORMATION**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

Art Unit: 1631

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: feme 5, 2002

Examiner Initials: CSM